UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

THOMAS RONKE PLAINTIFF v. BIOMET ORTHOPEDICS, LLC, and BIOMET, INC., and BIOMET MANUFACTURING CORP., and BIOMET U.S. RECONSTRUCTION, LLC DEFENDANTS	CIV 18-4136 **COMPLAINT**

Plaintiff, Thomas Ronke, by and through the undersigned attorneys, for his Complaint against Defendants, states as follows:

1. This is a product liability case involving a defective hip implant system. Plaintiff Thomas Ronke ("Plaintiff") had a Biomet Magnum M2a Metal-on-Metal Hip Systems ("Hip System") implanted in his hip joint. The Hip System suffers from defects that cause excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve, which in turn causes the hip implant to fail and the surrounding tissue and bone to die.

2. As a result of these defects, Plaintiff's Hip System had an unreasonably high risk of failing in his body, causing severe loosening of the device and/or toxic levels of cobalt and chromium, tissue and bone destruction, and the need for Plaintiff to undergo a complicated and risky surgery to remove and replace the defective implant.

PARTIES

3. Plaintiff Thomas Ronke is a citizen and resident of Tea, South Dakota, which is located in Lincoln County, South Dakota and is part of the District of South Dakota, U.S. District Court.

4. Defendant, Biomet Orthopedics, LLC, is, and at all times relevant to this Complaint was, an Indiana limited liability company, with its principal place of business in Warsaw, Indiana. Biomet Orthopedics, LLC is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Biomet, Inc., an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet Orthopedics, LLC is a citizen of Indiana.

5. Defendant, Biomet, Inc., is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet, Inc. is a citizen of Indiana.

6. Defendant, Biomet Manufacturing Corp., is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet Manufacturing Corp. is a citizen of Indiana.

7. Biomet U.S. Reconstruction, LLC, is, and at all times relevant to this Complaint was, an Indiana limited liability company, with its principal place of business in Warsaw, Indiana. Biomet U.S. Reconstruction, LLC is, and at all times relevant to this Complaint was, a wholly

owned subsidiary of Defendant, Biomet, Inc., an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet U.S. Reconstruction, LLC is a citizen of Indiana.

8. At all times mentioned, each Defendant was the representative, agent, employee, joint venturer, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, promotion, and sale of the Hip System that is the subject of this litigation. Therefore, it would be inequitable for any Defendant to escape liability for an obligation incurred as much for that Defendant's benefit as for the other.

9. All Defendants are collectively referred to herein as "Biomet."

JURISDICTION AND VENUE

10. This is a civil action of which U.S. District Court for the District of South Dakota has original jurisdiction under 28 U.S.C. section 1332 because it is between citizens of different states (as described above) and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interest. A typical revision surgery to repair a prosthetic hip device costs as much as $100,000.00 including hospital and doctor bills. Plaintiff's claims from his October 2017 revision surgery include his medical expenses, and also pain and suffering that relates to his long recovery from his revision surgery. These amounts easily exceed the $75,000.00 threshold.

11. Defendants are subject to jurisdiction within the District of South Dakota and this Court because:

a. Defendants are engaged in substantial and not isolated business activity within the State of South Dakota, including but not limited to Lincoln County;
b. Defendants' products, including the subject M2a Hip System, which it designed and manufactured was placed into the stream of commerce by

Defendant and was used within the State of South Dakota in the ordinary course of commerce, trade or use;

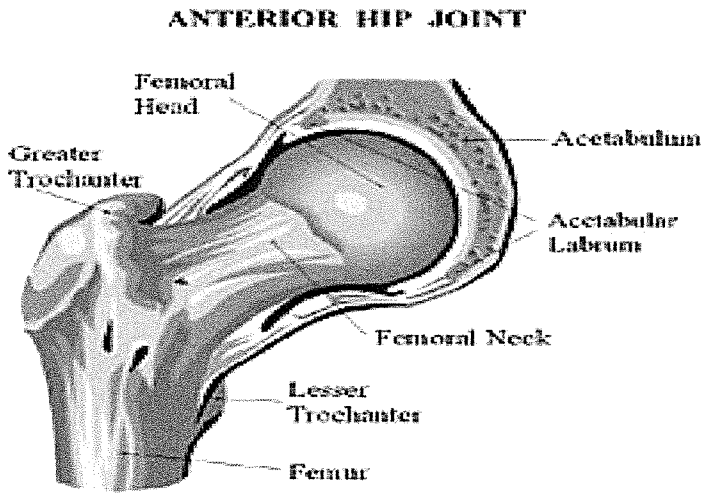
c. The subject M2a Hip System caused injury to persons, including Plaintiff, Thomas Ronke, within the District of South Dakota as a result of the tortious and wrongful acts and omission of the Defendants as set forth more fully herein; and
d. The Defendants maintain an office or agency within the State of South Dakota;
e. Upon information and belief, at all relevant times, Defendants committed tortious act(s) within the State of South Dakota out of which act(s) these causes of action arise.

12. Venue is proper in the U.S. District Court for the District of South Dakota pursuant to 28 U.S.C. §1391 because it is the judicial district in which a substantial part of the events or omissions giving rise to the claim occurred and all Defendants are subject to personal jurisdiction in this District.

FACTUAL BACKGROUND

A. The Hip System Is Defective and Was Not Adequately Tested

13. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.



14. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

15. The Hip System used in Plaintiff's surgery, described in greater detail below, suffers from a design or manufacturing defect that causes loosening of the device and/or excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter.

16. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, elevated levels of cobalt and chromium in the blood, heavy metal poisoning, pseudotumors, tissue necrosis, osteolysis, muscle wasting, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

17. Briefly, in the 1960s, the orthopedic device industry experimented with various metal-on-metal (hereafter "MoM") designs for hip implants. These designs call for a metal femoral head to articulate directly against the metal interior of an acetabular cup. The perceived benefit of MoM was the idea that metal was stronger than plastic, would last longer, and wear less. Further, the strength of the metal would theoretically allow for designs that increased range of motion.

18. However, by the mid-1970s, MoM hip implants were completely abandoned because the implants resulted in a high percentage of patients with poor clinical outcome, mostly as a result of the metal on metal articulation. The industry shifted in favor of utilizing polyethylene components.

19. Due to the limited use and subsequent complete abandonment of MoM technology by the mid-1970s, there had been almost no medical or scientific advancement in decades relating to understanding the *actual*, *clinical* risks associated with using MoM technology for hip implants.

20. Despite the early failure of metal-on-metal technology and despite the near complete lack of a *clinical* safety record due to the previous abandonment of the technology, Defendants designed, developed, promoted and manufactured the M2a metal-on-metal Hip System, which utilizes a MoM bearing surface.

21. The design of the Hip System was not sufficiently tested by Biomet, and it was never approved by the FDA as being safe or effective for its intended purpose.

22. Biomet chose to forgo clinical trials related to the risks of heavy metal poisoning prior to bringing its first metal-on-metal Hip System to market in 2001 despite receiving warnings from the medical and scientific community about risks of the same posed by the Hip System's MoM bearing surface during the design phase and was notified of the need conduct clinical testing

related to the release of metal ion's as early as 1995. The only system for which Biomet performed any pre-approval clinical testing was the M2a-Taper, and Biomet did not gather data about the harmful risks of metal ions as part of the study. Biomet failed to perform any pre-approval clinical testing for the similar M2a-38 and M2a-Magnum systems.

23. To avoid comprehensive testing of the Hip System, Biomet utilized the FDA's "510(k)" procedures to gain "clearance" to sell the Hip System in the United States.

24. The "510(k)" process does not provide "approval" for sale based on any analysis of clinical safety or efficacy, nor is this process designed to do so.

25. Instead, the "510(k)" process is a way to fast-track a product to the market based on an intended seller's representation that a product is "substantially equivalent" to products that were either previously "cleared" for sale through the same process or were grandfathered in before regulations requiring the pre-market testing of medical devices were adopted in 1976.

26. The FDA's "clearance" for the Hip System to be sold did not involve any extensive scrutiny for clinical safety and efficacy before sale and instead only required a showing of substantial equivalence to previously cleared devices (which also were not scrutinized for clinical safety before "clearance" for sale).

27. Biomet willfully and knowingly utilized the "510(k) clearance process" in an effort to mislead the orthopedic community, the public, and Plaintiff regarding the safety and efficacy of the Hip System.

28. Biomet knew or should have known that the safety and efficacy of the Hip Systems' predicate devices did not adequately support the safety or efficacy of the Hip System.

29. Despite the fact that Biomet failed to conduct comprehensive clinical testing of its metal-on-metal Hip System, including but not limited to the potential for release of metal ions

from the bearing surface, it has claimed that the Hip System offers extremely low wear rates compared to other hip replacements systems, and is safer than other MoM hip prostheses.

30. In fact, in a 2004 publication titled "Metal Ions – A Scientific Review," Biomet falsely concludes that: "Extensive research and years of clinical trials have failed to prove any cause for concern associated with the ion levels exhibited from metal-on-metal implants."[1]

31. In a heading on page 7 of the publication, Biomet went so far as to claim that: "Cobalt and Chromium may be beneficial to the body as established by research and listed by the US government."[2]

B. Biomet Sold the Hip Implant To Plaintiff After It Knew It Was Defective, That It Had Injured Others, And That It Could Injure Plaintiff.

32. It was not long after Biomet launched the Hip System that reports of failures began flooding into Biomet. For example, in August 2004, Biomet received a complaint that a patient had to undergo a surgery to remove and replace an M2a Magnum Hip System because it had failed after only 3 years. Biomet subsequently closed its investigation of this complaint.

33. Biomet would go on to receive hundreds of similar complaints reporting that the Hip System had failed, and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed MOM components.

34. Unfortunately, Biomet intentionally suppressed its rate of "adverse events reported to the FDA" with regards to the Hip System.

35. Biomet knowingly underreported complaints and revision surgeries about the Hip System to the FDA in an intentional scheme to mislead the public, the orthopedic community, and

[1] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf (Last viewed Apr. 17, 2018).
[2] *Id.*

Plaintiff about the safety and efficacy of the Hip System. Biomet further based its claims regarding the adverse event rate of the Hip System based on the underreported adverse event rates of the Hip System's predicate devices.

36. Biomet accomplished this, at least in part, by a pattern and practice of only reporting revision surgeries as adverse events to the FDA if patients who underwent a revision surgery *also* filed a lawsuit.

37. At all times relevant to this lawsuit, Biomet was aware that its pattern and practice of making the reporting of adverse events contingent upon whether the patient also filed a lawsuit relating to the adverse event would result in an unreasonable underreporting of adverse events across the patient population implanted with the Hip System as a whole.

38. To date, more than 350 reports of adverse events associated with the Hip System have been filed with the FDA. By the time Biomet sold the Hip System to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associated with the Hip System and other related MoM hip products. Consequently, Biomet was fully aware that some of its Hip Systems were defective and that dozens of patients already had been injured by that defect. Based on this information, Biomet should have recalled the Hip System before it was sold to Plaintiff. At minimum, Biomet should have stopped selling the Hip System when it became aware that it had catastrophically failed in several patients.

39. As numerous failures the of Hip System were reported to Biomet, it continued to actively promote, market and defend its defective product. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal implants. These brochures were given to doctors around the world to encourage them to use the Hip System.

40. As a result of Biomet Defendants' efforts to fraudulently conceal and distort information related to the safety record for the Hip System, the orthopedic community and Plaintiff's surgeon, in particular, did not and could not have knowledge or sophistication equal to the Biomet Defendants with regards to the risks of the Hip System. Because metal-on-metal hip systems typically do not generate harmful levels of metal ions until many years after implantation, and because Biomet failed to recall the systems, Plaintiff could not have known of the potential legal claim related to Plaintiff's failed hip until, at the very least, the date of Plaintiff's revision surgery. Plaintiff's claim is therefore well within the applicable statute of limitations.

41. Biomet was also made aware of failures of the Hip System through interactions and communications with customer surgeons. Biomet did not take proper action in response to these interactions and communications, including but not limited to reporting relative adverse event reports to the FDA.

42. Despite knowing or being in a position where they should have known, of the unreasonable risks associated with the Hip System, Biomet continued to market and sell the Hip System throughout the United States. Biomet failed to provide adequate warnings to the public or the medical community regarding the risks associated with the Hip System. Rather, Biomet continued to falsely claim to the medical community and the public the Hip System was safe.

43. Upon information and belief, further false statements by Biomet regarding the Hip System include, but are not limited to, the following:

a. Biomet falsely claimed that the Hip System was a safe and effective hip replacement system.
b. Biomet falsely claimed that the Hip System was clinically safe and effective based on laboratory tests.
c. Biomet falsely claimed that the Hip System was clinically safe and effective based on clinical tests.
d. Biomet falsely attributed data regarding clinical failures of the Hip System to

improper patient selection by surgeons.

e. Biomet falsely attributed data regarding clinical failures of the Hip System to improper surgical technique by surgeons.

f. Biomet falsely attributed data regarding clinical failures of the Hip System to patient characteristics.

g. Biomet falsely claimed the clinical existence of a run-in period for the Hip System.

h. Biomet falsely claimed that the metal wear clinically produced by the Hip System during the theoretical run-in period was within safe limits.

i. Biomet falsely claimed that metal wear clinically released from the Hip System is reduced after a theoretical run-in period of three years.

j. Biomet falsely presented clinical research data from within the theoretical run-in period as being indicative of the long-term clinical safety and efficacy of the Hip System.

k. Biomet falsely claimed knowledge of clinically safe limits for metal wear.

l. Biomet falsely attributed metal wear production to surgical technique and environmental contaminants to the exclusion of device related factors.

m. Biomet falsely attributed clinical reactions to metal wear to patient hyper-sensitivity.

n. Biomet falsely claimed the Hip System was highly wear-resistant.

o. Biomet falsely claimed the Hip System exhibits less metal wear than other competing types of hip implants.

p. Biomet falsely claimed they could not draw conclusions regarding the safety or efficacy of the Hip System even after analyzing reports of revisions and explanted components.

q. Biomet falsely claimed that the design differences between the Hip System and other MoM hips made the Hip System safer and more effective than other MoM hips.

r. Biomet falsely claimed that the design differences between the Hip System and other MoM hips made the Hip System a clinically safe and effective hip replacement system.

44. In addition to falsely claiming that the Hip system was safe, Biomet omitted a great deal of material information regarding the safety and efficacy of the Hip System to Plaintiff, Plaintiff's surgeon, and the orthopedic community including, but not limited to:

a. The lack of evidence to support the clinical existence of fluid film lubrication during a large percentage of normal, everyday use of the Hip System;

b. The clinical existence of greater histological reaction to the comparatively smaller wear particles produced by the Hip System as compared to the larger particles produced by Metal on Polyethylene ("MoP") hips that were available at the same time.

c. The likelihood of a smaller volume of metal particles from the Hip System producing greater negative clinical effects than a larger volume of plastic particles from other MoP hips available at the same time;

d. A large number of Hip System failures were assumed to not be device-related despite a lack of adequate investigation;

e. Hip System design characteristics were a known potential cause of the complaints and revisions being reported;

f. Long-term clinical studies of the Hip System were purposefully avoided or omitted when promoting the long-term outcome of the Hip System;

g. "Hypersensitivity" to the Hip System and/or metal ions released by the same is defined solely by the occurrence of a negative outcome and not by a pre-disposition for a negative outcome;

h. Citations to data regarding the purported long-term success of past generations of MoM hips focused solely on the percentage of those devices not revised after a certain period of time, omitting data regarding those that failed and required revision;

i. Though metal ions can be excreted through the urine, the excretion cannot be enough to offset the amount of metal ions and wear being released into the body;

45. Biomet's reason to conceal the defect in its Hip System is clear. Hip implant sales are critically important to Biomet. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet look appealing to investors. The company ultimately was purchased by a private equity firm in 2007 for $10 billion. More recently, in April 2014, managers at Biomet announced yet another sale, this time to competitor Zimmer Holdings, Inc., in a deal valued at $13.35 billion. Throughout this time period, Biomet was faced with a critical defect in one of its most profitable hip implant systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the

expense of patient safety, Biomet decided that it would continue to promote, market, and sell its various MoM Hip Systems despite the fact that it knew these products were defective.

C. Plaintiff's Hip Systems Were Defective.

46. On or about March 4, 2010, Plaintiff underwent left hip replacement surgery by Peter K. Rodman M.D. at Sioux Falls Specialty Hospital in Sioux, South Dakota, during which a Biomet M2a-Magnum metal-on-metal prosthesis, was implanted in his left hip joint. By this time, reports of adverse events associated with the M2a-Magnum, M2a-38, M2a-Taper and other Biomet devices had been filed with the FDA and Biomet knew that the product was subject to failure due to excessive metal-on-metal wear and other factors. These hip systems fail at a rate approaching 20 percent after just ten years, far in excess of the acceptable rate for all hip devices. But Biomet refused to disclose that information to Plaintiff, his physicians, or the public.

47. Instead, Biomet misrepresented to Plaintiff and his orthopedic surgeon that the Hip System was safe and effective. In reliance on these representations, Plaintiff's orthopedic surgeon made the decision to use the Hip System. If it were not for the misrepresentations made by Biomet, Plaintiff's orthopedic surgeon would not have used the Biomet Hip System.

48. As a result of the defective design, manufacture and composition of the Hip System, and its accompanying warnings and instructions (or lack thereof), Plaintiff's hip implant caused him severe pain and he was forced to undergo costly and painful revision surgery on October 16, 2017, on the left side, by Michael J. Adler, M.D. at Sioux Falls Specialty Hospital in Sioux Falls, South Dakota.

49. Having to go through a revision surgery has subjected Plaintiff to much greater risks of future complications than he had before the revision surgery.

50. Several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al.* Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

51. As a direct and proximate result of the failure of his defective Hip Systems and Biomet's wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed $75,000 jurisdictional minimum of this court.

COUNT I
(Strict Product Liability)

52. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

53. Biomet designed, manufactured, promoted, distributed, marketed, and sold the Hip System.

54. At all times material hereto, the Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was expected to reach, and did reach,

prescribing physicians and consumers, including Plaintiff and his physician, without substantial change in the condition in which it was sold.

55. At all times material hereto, the Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

(a) When placed in the stream of commerce, the Hip System contained manufacturing defects, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

(b) When placed in the stream of commerce, the Hip System contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

(c) The Hip System was insufficiently tested; and

(d) The Hip System was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff and his physicians of the full nature or extent of the risks associated with its use.

56. Biomet knew or should have known of the dangers associated with the use of the Hip System, as well as the defective nature of the Hip System. Despite this knowledge, Biomet continued to manufacture, sell, distribute, promote and supply the Hip System so as to maximize sales and profits at the expense of the public health and safety. Biomet's conduct was done in

conscious disregard of the foreseeable harm caused by the Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

57. Plaintiff and his surgeon used the M2a Magnum Hip Systems as directed for its intended purpose.

58. At all times herein mentioned, the Hip System was defective, and Biomet knew that it was to be used by the user without inspection for defects therein. Moreover, at the time of the use of the subject products, neither Plaintiff nor his physician knew or had reason to know of the existence of the aforementioned defects. Neither Plaintiff nor his physicians could have discovered the defects in the Hip System through the exercise of reasonable care.

59. The Hip System had not been materially altered or modified prior to its implantation in Plaintiff.

60. As a direct and proximate result of the failure of the defective Hip System, Plaintiff suffered the injuries and damages as described herein.

COUNT II
(Negligence)

61. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

62. At all times herein mentioned Biomet had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.

63. Biomet maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the Hip System.

64. Biomet, maliciously, recklessly and/or negligently made misrepresentations about the safety and effectiveness of the Hip System to Plaintiff and his orthopedic surgeon. In reliance on these misrepresentations, Plaintiff's orthopedic surgeon decided to use the Hip Implant in Plaintiff's surgery. If it was not for the misrepresentations by Biomet, Plaintiff's orthopedic surgeon would not have used the Hip System in Plaintiff's surgery.

65. Biomet maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Plaintiff and his physicians as to the risks of the Hip System.

66. Biomet maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the Hip System when they knew or should have known of said risks.

67. Biomet's conduct was done in conscious disregard of the foreseeable harm caused by the Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

68. As a result of Biomet's wrongful conduct, Plaintiff suffered injuries and damages as alleged herein.

COUNT III
(Breach of Implied Warranties)

69. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

70. Prior to the time that the Hip System was used by Plaintiff, Biomet impliedly warranted to Plaintiff and his physicians that the Hip System was of merchantable quality and safe and fit for the use for which it was intended.

71. Plaintiff's physicians were and are unskilled in the research, design and manufacture of the Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Biomet in using the Hip System.

72. The Hip System was neither safe for its intended use nor of merchantable quality, as warranted by Biomet, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

73. Biomet, by selling, delivering and/or distributing the defective Hip System to Plaintiff, breached the implied warranty of merchantability and fitness and caused Plaintiff pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

74. As a result of the aforementioned breach of implied warranties by Biomet, Plaintiff suffered injuries and damages as alleged herein.

COUNT IV
(Breach of Express Warranty)

75. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

76. At all times herein mentioned, Biomet expressly warranted to Plaintiff and his physicians, by and through statements made by Biomet or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned Hip System was safe, effective, fit and proper for its intended use.

77. In utilizing the aforementioned Hip System, Plaintiff and his physician relied on the skill, judgment, representations and foregoing express warranties of Biomet.

78. Said warranties and representations were false in that the aforementioned Hip System was not safe and was unfit for the uses for which it was intended.

79. As a result of the foregoing breach of express warranties by Biomet, Plaintiff suffered injuries and damages as alleged herein.

COUNT V
(Violation of South Dakota Consumer Protection Act)
S. D. Codified Laws § 37-24-1 et. seq.

80. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

81. Defendants are liable to the Plaintiff pursuant to the South Dakota Consumer Protection Act. As a direct and proximate result of Defendant's wrongful acts and omissions, Plaintiff has sustained and will continue to sustain damages consisting of: past and future lost wages, medical, permanency and incidental expenses, according to proof; past and future general damages for pain and suffering, according to proof.

82. In the course of the transactions that are the subject of this lawsuit, Defendant engaged in the following unfair and deceptive acts, methods or practices:

a. Causing a probability of confusion or misunderstanding about the source, sponsorship, approval, or certification of its services;

b. Representing that its services have sponsorship, approval, characteristics, and benefits that they do not have;

c. Representing that its services were of workmanlike quality when, in fact they were not;

d. Causing a probability of confusion or of misunderstanding concerning Plaintiff's legal rights, obligations, or remedies;

e. Failing to reveal material facts, the omission of which tended to mislead or deceive Plaintiff, and which could not reasonably be known by the Plaintiff;

f. Taking or arranging for the consumer to sign an acknowledgment, certificate, or other writing affirming acceptance, delivery, compliance with a requirement of law, or other performance, when Defendant knew or had reason to know that the statement was not true;

g. Entering into a consumer transaction in which Plaintiff purportedly waived a right, benefit, or immunity provided by law, without conspicuous disclosure and without Plaintiff's specific consent;

h. Failing to provide promised benefits, including benefits arising by operation of law;

i. Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner; and

j. Such other and further acts or omissions as may be determined through further investigation and discovery.

83. Upon information and belief, the violations described above were not the result of bona fide error, in that Defendant did not have procedures in place designed to prevent injury to Plaintiff from their defective product, the defectiveness of which the Defendant had reason to know and Defendant has engaged in similar misconduct in connection with sales of other defective hip replacement implants.

84. As a result of the Defendant's actions described above, Plaintiff has suffered a loss within the meaning of the Act and is also entitled to statutory damages and attorney fees as provided in the Act.

85. Plaintiff did not become aware of the connection and/or nexus between his injuries and the above-described negligent design of the Biomet Hip System until his first revision surgery.

PRAYER FOR RELIEF

THEREFORE, Plaintiff demands judgment for the following:

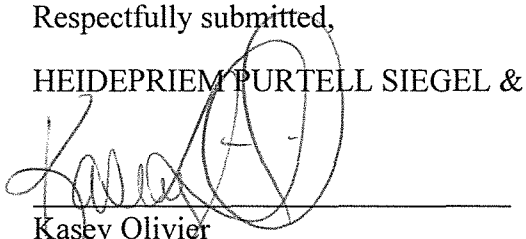
1. Past and future lost wages, medical, permanency and incidental expenses, according to proof;
2. Past and future general damages for pain and suffering, according to proof;
3. Punitive and exemplary damages in an amount to be determined at trial;
4. Prejudgment and post judgment interest;
5. Costs to bring this action; and
6. Such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the Plaintiffs demand trial by jury in this action of all issues so triable.

Respectfully submitted,

HEIDEPRIEM PURTELL SIEGEL & OLIVIER LLP



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